

REMARKS

Claims 1-26 are currently pending in this application. Claims 1-19 have been withdrawn from consideration. The Office Action rejected claims 20-26. Claim 22 has been amended.

Claim 22 has been amended to correct a typographical error. Specifically, the word "spontaneously" has been deleted and replaced with the word --simultaneously--. Support for this amendment can be found in the specification at page 11, lines 16-19.

No new matter has been added by this amendment; therefore, Applicants respectfully request that examination continue on the claims as presented herein.

Objections to the Drawings:

Objection under 37 C.F.R. 1.83(b):

The Office Action objected to the drawings under 37 C.F.R. 1.83(b), alleging that the drawings were incomplete. Specifically, the Office Action asserted that Figures 2 and 3 do not provide a clear illustration of the prosthesis.

Applicants respectfully disagree with this objection. As an initial matter, the Office Action has failed to provide any reason why Figures 2 and 3 are believed to be unclear and/or incomplete. Instead, the Office Action has merely asserted an unsupported conclusion that Figures 2 and 3 do not clearly illustrate the prosthesis. Thus, without any information or reasoning as to why Figures 2 and 3 are considered unclear and/or incomplete, Applicants cannot specifically address, either by argument or amendment, the stated objection.

Moreover, it is respectfully submitted that Figures 2 and 3 are clearly illustrative of the prosthesis. In particular, both figures show bottom views of prosthesis 5. A first layer 7 and a second layer 8 are plainly identified, as is a self-shaping material 15 in the second layer. A second film 12 and fill opening 16 are also plainly indicated in these figures. Further, Figure 3 shows an impression in the self-shaping material 15. So in light of the above, Applicants respectfully maintain that Figures 2 and 3 do clearly illustrate a portion of the prosthesis and that the objection should therefore be withdrawn.

Objection under 37 C.F.R. 1.83(a):

The Office Action also objected to the drawings under 37 C.F.R. 1.83(a), alleging that the drawings do not show every feature specified in the claims. Specifically, the Office Action asserted that the drawings lack “the features of the interstitial film between the first and second film along the common side edges.”

Applicants respectfully disagree with this objection because these features are indicated in the figures. In particular, claim 20 recites “a first film envelope configured to define a first interior volume; and a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall.” As shown in the figures, the first film envelope referred to in claim 20 is indicated by reference number 8, and the second film envelope is indicated by reference number 7. The cross-section of these two envelopes is visible in Figure 4, where first film envelope 8 is shown as being defined by films 11 and 12, and second film envelope 7 is shown as being defined by films 9, 11, and 12. Thus, as is plainly visible from Figure 4, the second film envelope is joined to the first envelope along a common side edge, and the common interstitial film wall shared by the two envelopes is the film indicated by reference number 11. (*See also* the specification at page 10, line 28 to page 11, line 4). Accordingly, it is respectfully submitted that the features of the interstitial film wall between the first and second film along the common side edge are indicated in the figures and the rejection should therefore be withdrawn.

Rejections under 35 U.S.C. § 112

The Office Action rejected claims 20-24 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In particular, the Office Action asserted that claims 20 and 21 are incomplete in that the claims, as worded, would not result in a prosthesis having a first and a second interior volume because such a process would require three films to define the two volumes.

Applicants respectfully submit that claims 20 and 21 are sufficiently complete to describe a prosthesis having a first and a second interior volume. Claim 20 recites “a first film envelope configured to define a first interior volume and a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume.” One of ordinary skill in the art would reasonably understand such an arrangement to result in a prosthesis having at least three layers defining two interior volumes. That is, when one film envelope defining one interior volume is joined to another film envelope along a common side edge, a second interior volume is defined. And as claim 20 recites, “said second film envelope and said first film envelope share a common interstitial film wall.” Thus, there are at least three film layers present in the prosthesis: the exterior of the first film envelope, the exterior of the second film envelope (which is joined to the first film envelope), and the common interstitial layer shared between the two envelopes. See also Figure 4 and the specification at page 11, lines 24-26; where the three film layers 9, 11, and 12 define the two interior volumes 7 and 8. Consequently, Applicants respectfully submit that claims 20 and 21 are sufficiently worded to define a prosthesis having a first and a second interior volume and that this rejection should therefore be withdrawn.

As for claim 22, the Office Action asserted that it is not clear what is meant by the word “spontaneously.” In amended claim 22, a typographical error has been corrected by replacing the word “spontaneously” with the word “simultaneously.” Therefore, this rejection is believed to be obviated.

As for claims 23-24, the Office Action asserted that it is not clear how the word “interstitial” further defines the film and that the use of the term “interstitial” is not commensurate with its dictionary definition.

Applicants would like to point out that “interstitial film” is a term consistently used throughout the specification to define the film between the first and second envelopes (*i.e.*, layers, regions, or volumes). See *e.g.*, page 9, lines 19-22. Also, the interstitial film is clearly labeled reference number 11 in Figure 4. Because this term is defined and supported by the specification and drawings, one of ordinary skill in the art would understand its meaning with a reasonable degree of particularity and distinctness. Therefore, Applicants respectfully submit

that this rejection should be withdrawn.

Rejection under 35 U.S.C. §102/103:

The Office Action rejected claims 20-26 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,902,335 to Snyder, Jr. (hereinafter “Snyder”). Specifically, the Office Action asserted that Snyder discloses a process for making a breast prosthesis having a first and second chamber that anticipates or, in the alternative, renders obvious the claimed breast prosthesis. Applicants respectfully traverse this rejection.

Snyder discloses a breast prosthesis having an outer chamber and an inner chamber (*see e.g.*, col. 1, ll. 52-62). Snyder further discloses that both chambers of the prosthesis are filled with silicone gel (*see e.g.*, col. 3, ll. 18-20 and 37-41); however, the inner chamber additionally contains a density reducing agent (*see e.g.*, col. 2, ll. 17-31). The density reducing agent, after curing and cross-linking of the silicone gel, makes the silicone gel less dense in the inner chamber but substantially as stiff as the silicone gel in the outer chamber (*see col.* 5, ll. 10-15 and 36-37).

The present invention is novel over Snyder. Claim 20 recites the use of a “self-shaping dispersion” in the first interior volume. In contrast, Snyder discloses only silicone gel with a density reducing agent in the inner chamber of the disclosed prosthesis. This reduced density silicone gel of Snyder is not a self-shaping dispersion, as is recited in claim 20. Rather, the reduced density silicone gel is a cross-linked gel that is as stiff or stiffer than the silicone gel used in the outer layer (col. 5, ll. 46-48). Therefore, because Snyder does not disclose a process for preparing a breast prosthesis having a self-shaping dispersion in the first interior volume, it does not anticipate the claimed invention.

Furthermore, the claimed invention is nonobvious in view of Snyder. As noted above, the claimed process uses a self-shaping dispersion in the first interior volume. Snyder, on the other hand, only discloses the use of a silicone gel that has a density reducing agent for the purpose of reducing the weight of the prosthesis. As such, Snyder is absent any motivation, suggestion, or teaching regarding the use of a self-shaping dispersion as recited in claim 20. In

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fact, Snyder teaches away from the use of self-shaping dispersions in the inner layer. For example, in col. 5, ll. 10-15 and 46-48, Snyder teaches that the material in the inner layer has substantially the same stiffness or is stiffer than the outer layer, which, as Snyder discloses, has the feel and stiffness of a human breast tissue. Thus, such a teaching actually discourages the skilled artisan from using a material in the inner layer of a breast prosthesis that would be self-shaping. Accordingly, because Snyder does contain the requisite motivation or suggestion for using a self-shaping dispersion, this reference fails to render the claimed process obvious.

PETITION FOR EXTENSION OF TIME

It is respectfully requested that an extension of time for three months granted in accordance with the provisions of 37 C.F.R. Section 1.136, extending the time to take action this from October 27, 2003, to and including February 27, 2004. A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$950.00 is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

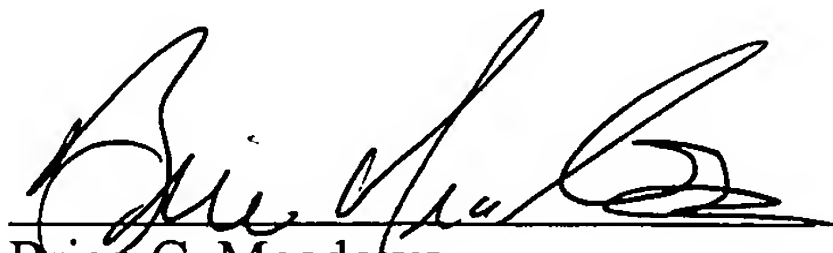
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CONCLUSION

In light of the above amendments and arguments, the application is believed to be in condition for allowance; accordingly, Applicants respectfully seek notification of same.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

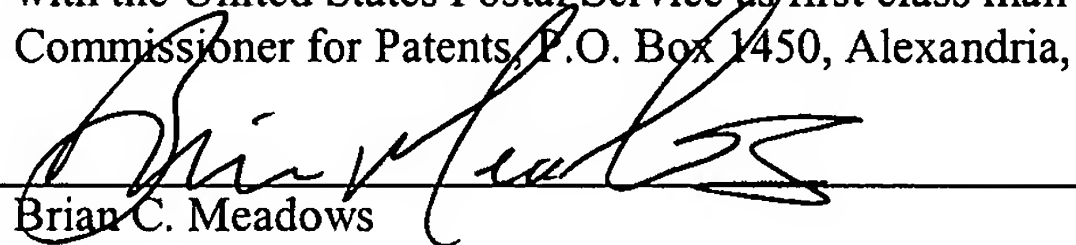


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CERTIFICATE OF MAILING

I hereby certify that this document and any documents referenced herein as being enclosed herein is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.


Brian C. Meadows

February 25, 2004
Date